

REMARKS

FORMAL MATTERS:

Claims 1-13 and 15-19 were examined and rejected. Claims 3, 4, 10 and 11 were previously withdrawn. Claims 14 and 20-42 were previously canceled without prejudice.

Claim 1, 6, 7, 13 and 18 have been amended and claim 43-47 have been added. Support for these amendments is found throughout the specification, drawings and in the claims as originally filed. In particular, the amendments to independent claims 1 and 18 are supported by original claim 7 and paragraphs 0023 and 0039. The amendments to claim 6 and 13 are clerical in nature only. The amendment to claim 7 is supported by Figs. 3B, 4B, 5 and 7B which clearly depict the claimed device extending between the leaflets. Newly added claims 43 and 44 are supported by the same figures and throughout the specification which describes a device which is not attachable to or engagable with the annulus of the valve. Newly added claims 45 and 46 are particularly supported by paragraphs 0023, 0039 and 0045. Newly added claim 47 is supported by paragraphs 0048 and 0050.

As no new matter has been added by way of these additions and amendments(s) to the claims, entry thereof by the Examiner is respectfully requested.

Claims 1, 2, 5, 6, 7, 8, 9, 12, 13, 15-19 and 43-47 are pending in the application.

REJECTIONS UNDER §102

The claims are directed to implantable devices and systems for repairing regurgitant cardiac valves having two or more leaflets and a subvalvular structure wherein at least one leaflet has a prolapsing segment. The device comprises a structure for attachment to the prolapsing leaflet at the prolapsing segment without affecting the mobility of the prolapsing leaflet. The structure defines a coaptation surface against which an opposing leaflet coapts during systolic contraction of the heart whereby the coaptation between the leaflets is normalized. The coaptation surface is configured to extend freely beyond a free margin of the prolapsing segment when the structure is operatively implanted within the valve.

Claims 1, 2, 5, 7-9, 12, and 16-19 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Streeter (US 2002/065554).

Streeter's apparatus is affixed to the annulus of a cardiac valve and not to the prolapsing leaflet. There is no disclosure or teaching in Streeter's disclosure to suggest otherwise. In the Office Action, the Examiner states that "the Streeter device is capable of being attached to the valve leaflets in that it can be attached to the annulus and extends over one or both leaflets of the heart valve." "Extending" over a leaflet is distinctly different than "attachment" to a leaflet. The shear bulkiness of Streeter's device makes it inappropriate for attachment to a leaflet. While it is physically possible to attach the Streeter device to a leaflet, as the Examiner suggests (by looping sutures around the structure and extending them through the leaflet), such leaflet attachment would certainly affect the mobility of the leaflet. Moreover, such attachment would not only defeat the purpose and function of the Streeter device but would mostly likely make the valve incompetent. Should the Examiner wish, a declaration from the inventor, an experienced cardiac surgery, can be presented to support such position.

Additionally, as amended, claim 1 clarifies that the coaptation surface extends freely beyond the free margin of the prolapsing segment. No such structure is disclosed, taught or suggested by Streeter.

Accordingly, Streeter does not anticipate or make obvious the claimed subject matter. Withdrawal of the rejection and allowance of claims 1, 2, 5, 7, 8, 9, 12, 16-19 and newly added claims 43-47 (all of which are dependent on allowable claim 1) are respectfully requested.

Claims 1, 5, 6, and 16 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Gabbay (US 6,419,695).

The apparatus disclosed by Gabbay is adapted for attachment to the annulus of a heart valve and acts as a prosthetic leaflet. In particular, Gabbay teaches that the apparatus includes an annular base which is attached to the valve annulus. However, as with Streeter, nowhere in the specification does Gabbay disclose or teach attaching the apparatus to the leaflet itself. The arguments presented above with respect to Streeter regarding the differences between attachment to a valve versus extension over a valve apply to Gabbay as well.

Moreover, as amended, claim 1 clarifies that the structure, when implanted, provides a coaptation surface for the prolapsing leaflet without affecting the mobility of that leaflet. Gabbay's device functions quite oppositely. It not only affects the mobility of the prolapsing leaflet, it completely immobilizes it, removing it altogether from participation in the valve's function.

Still yet, claim 1 further clarifies that the coaptation surface of the structure extends freely beyond the free margin of the prolapsing segment. Gabbay's device is fixed in place and no portion of it

extends freely. Applicant notes that this limitation was presented in original claim 7 which the Examiner, correctly so, did not reject in view of Gabbay.

Accordingly, Gabbay does not anticipate or make obvious the claimed subject matter. Withdrawal of the rejection and allowance of claims 1, 5, 6, and 15 and newly added claims 43-47 (all of which are dependent on allowable claim 1) are respectfully requested.

REJECTIONS UNDER §103(A)

Claims 13 and 15 have been rejected as being unpatentable over Streeter. For at least the reasons presented above in response to the rejection of claim 1 as being anticipated by Streeter, claims 13 and 15 are patentable over Streeter.

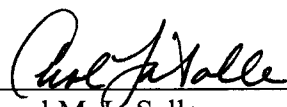
CONCLUSION

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,
BOZICEVIC, FIELD & FRANCIS LLP

Date: March 24, 2006

By: 
Carol M. LaSalle
Registration No. 39,740

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, California 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231